

Assembly Bill No. 1060

Passed the Assembly September 10, 2015

Chief Clerk of the Assembly

Passed the Senate September 3, 2015

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2015, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to add and repeal Chapter 2 (commencing with Section 101990) to Part 6 of Division 101 of the Health and Safety Code, relating to cancer.

LEGISLATIVE COUNSEL'S DIGEST

AB 1060, Bonilla. Cancer clinical trials.

Existing law establishes the scope and function of the California Health and Human Services Agency, which includes departments charged with administering laws pertaining to public health and social services, among other things. Existing law also establishes the Inclusion of Women and Minorities in Clinical Research Act, which is designed to promote the inclusion of women and minority groups in clinical research, including clinical trials.

This bill, until January 1, 2022, would establish the Cancer Clinical Trials Foundation in the Health and Human Services Agency, to be governed by a board of trustees. Members of the board would be appointed as specified. The bill would also create the Cancer Clinical Trials Fund, to be used to administer a grant program. The bill would limit the amount the agency may spend to establish the foundation to \$300,000 of appropriated funds, to be repaid by January 1, 2021, but would otherwise prohibit General Fund moneys from being used for the foundation. The bill would authorize the board to solicit and receive money, as specified, and would authorize the agency to apply for federal funds for this purpose. The bill would require the board, upon contribution of at least \$500,000 to the fund, to establish the Cancer Clinical Trials Grant Program, in order to increase patient access to cancer clinical trials in specified populations. The bill would require that grant money be used for designated purposes, and would also require grant recipients to report to the board. The bill would require the board to report to the Legislature, as specified. This bill would make related findings.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

(a) Almost 50 percent of clinical trial studies are not finished in time due to low patient participation, recruitment and navigation difficulties, and other barriers for patients. Due to economic and socioeconomic circumstances and lack of patient knowledge, clinical oncology trial participation and retention are both very low as they relate to eligible participants.

(b) Overall, only 3 percent of eligible cancer patients participate in clinical trials, and of those only 5 percent of trial participants are from racial or ethnic minority communities.

(c) One barrier that prevents patients from participating in federal Food and Drug Administration clinical trials is finances. Patients of low to moderate income are often unable to bear the burden of the ancillary costs of participating, such as airfare, lodging, rental cars, and fuel.

(d) The American Medical Association conducted a study on cancer trial participation. The study found that from 1996 to 2002, of the 75,215 patients enrolled in the National Cancer Institute trials for breast, lung, colorectal, and prostate cancers, only 3.1 percent were Hispanic, 9.2 percent were Black, and 1.9 percent were Asian or Pacific Islanders, while 85.6 percent were White. This lack of diversity is of concern because of its impact on researchers' ability to evaluate the effect of new treatments on different populations. It also speaks to a lack of access to potentially lifesaving trials for a large portion of the population.

(e) It is the intent of the Legislature to establish a program to enable willing patients of low to moderate income to participate in cancer clinical trials in order to boost participation rates, ensure these trials are widely accessible, improve the development of cancer therapies, and enhance innovation.

SEC. 2. Chapter 2 (commencing with Section 101990) is added to Part 6 of Division 101 of the Health and Safety Code, to read:

CHAPTER 2. CANCER CLINICAL TRIALS

101990. (a) "Board" means the Board of Trustees of the Cancer Clinical Trials Foundation.

(b) "Foundation" means the Cancer Clinical Trials Foundation.

(c) "Fund" means the Cancer Clinical Trials Fund.

101991. (a) The agency shall establish a nonprofit public benefit corporation, to be known as the Cancer Clinical Trials

Foundation, that shall be governed by a board consisting of a total of five members. Three members shall be appointed by the Governor. Of these members, one shall be from a public cancer research institution, and one shall be from a private cancer research institution. One member shall be appointed by the Speaker of the Assembly. One member shall be appointed by the President pro Tempore of the Senate.

(b) All persons appointed to the board shall have an interest in increasing access to cancer clinical trials and the ability and desire to solicit funds for the purpose of increasing access to clinical trials as provided in this chapter.

(c) The Governor shall appoint the president of the board from among those members appointed by the Governor, the Speaker of the Assembly, and the President pro Tempore of the Senate.

(d) The foundation, or an authorized representative thereof, shall apply for tax exempt status under Section 501(c)(3) of the Internal Revenue Code.

(e) Members of the board shall serve without compensation but shall be reimbursed for any actual and necessary expenses incurred in connection with their duties as members of the board.

(f) The foundation shall be subject to the Nonprofit Public Benefit Corporation Law (Part 2 (commencing with Section 5110) of Division 2 of Title 2 of the Corporations Code).

(g) The California Health and Human Services Agency shall determine which department in the agency shall administer the foundation.

101992. (a) Of the members of the board first appointed by the Governor pursuant to Section 101991, one member shall be appointed to serve a two-year term, one member shall be appointed to serve a three-year term, and one member shall be appointed to serve a four-year term.

(b) Of the members of the board first appointed by the Speaker of the Assembly and the President pro Tempore of the Senate pursuant to Section 101991, each member shall be appointed to serve a four-year term.

(c) Upon the expiration of the initial appointments for the board, each member shall be appointed to serve a four-year term.

101993. (a) There is hereby created in the State Treasury the Cancer Clinical Trials Fund. Moneys in the fund shall be used for

the administration and support of the program created pursuant to this chapter upon appropriation of the Legislature.

(b) The Cancer Clinical Trials Foundation may solicit and receive funds from business, industry, foundations, and other private and public sources for the purpose of administering the Cancer Clinical Trials Grant Program to increase patient access to cancer clinical trials.

(c) The agency may apply for federal funds for the foundation.

(d) The board shall use no more than 20 percent of funds made available for the Cancer Clinical Trials Grant Program for administrative costs.

101993.5. (a) The agency may not spend more than three hundred thousand dollars (\$300,000) of moneys appropriated to the agency to establish the foundation.

(b) Any money used to establish the foundation shall be paid back to the agency on or before January 1, 2021, from moneys donated to the Cancer Clinical Trials Fund.

(c) After the initial investment authorized by subdivision (a), no General Fund moneys shall be used to operate the foundation.

101994. (a) Upon contribution of at least five hundred thousand dollars (\$500,000) to the foundation, the board shall establish the Cancer Clinical Trials Grant Program to increase patient access to cancer clinical trials in underserved or disadvantaged communities and populations, including among women and patients from racial and ethnic minority communities. The board shall determine the criteria to award grants, and may award grants to either or both of the following:

(1) Public and private research institutions and hospitals that conduct cancer clinical trials approved by the federal Food and Drug Administration.

(2) Nonprofit organizations described in Section 501(c)(3) of the Internal Revenue Code of 1954 that are exempt from income tax under Section 501(a) of that code and that specialize in direct patient support for improved clinical trial enrollment and retention.

(b) Grants awarded pursuant to subdivision (a) shall be used for activities to increase patient access to cancer clinical trials, including, but not limited to, any of the following:

(1) Patient navigator services or programs.

(2) Education and community outreach.

(3) Patient-friendly technical tools to assist patients in identifying available clinical trials.

(4) Translation and interpretation services of clinical trial information.

(5) Counseling services for clinical trial participants.

(6) Well-being services for clinical trial participants, including, but not limited to, physical therapy, pain management, stress management, and nutrition management.

(7) Payment of ancillary costs for patients and caregivers, including, but not limited to:

(A) Airfare during the clinical trial.

(B) Lodging during the clinical trial.

(C) Rental cars during the clinical trial.

(D) Fuel during the clinical trial.

(E) Local transportation via bus, train, or other public transportation during the clinical trial.

(F) Meals during the clinical trial.

(G) Child care costs during the clinical trial.

(c) If the foundation does not receive five hundred thousand dollars (\$500,000) or more by January 1, 2021, moneys remaining after the repayment required pursuant to subdivision (b) of Section 101993.5 shall be returned to the donors on a pro rata basis.

(d) If the grant program is established pursuant to this section, all moneys in the fund shall be awarded by grant prior to the repeal of this chapter.

101995. (a) Grant recipients shall report to the board to ensure the appropriate use of funds within one year of receiving a grant.

(b) (1) The board shall report to the Legislature to ensure the appropriate use of the funds. The report shall include accountability measures, including, but not limited to, a description of how the funds were used, an evaluation of the grant program, and recommendations for the program. This report shall be submitted by January 1, 2020.

(2) The requirement for submitting a report imposed under paragraph (1) is inoperative on January 1, 2024, pursuant to Section 10231.5 of the Government Code.

101996. This chapter shall remain in effect only until January 1, 2022, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2022, deletes or extends that date.

Approved _____, 2015

Governor